REMARKS

Claims 14 and 53 are amended. Claims 1-53 are pending.

In response to the Restriction Requirement mailed October 5, 2006, Applicant provisionally elects, with traverse, the invention of claims 1-2, 5-9, 13, 15-23, and 28-32 (Group IA), directed to a method of identifying one or more agents with dual therapeutic activity in mammalian cells, e.g., an agent that inhibits or treats one or more symptoms of a disease which is associated with aberrant expression or activity of epithelial sodium channels (ENaC) and enhances the efficacy of a gene therapy vector.

With regard to the election of species from species i-iv (antibiotic, chemotherapeutic, lipid lowering compound, and food additive, respectively) Applicant provisionally elects, with traverse, specie i (an antibiotic).

With regard to the election of species from epoxomicin, doxorubicin, doxil, daunorubicin, idarubicin, epirubicin, aclarubicin, camptothecin, simvastatin, tannic acid, and cisplatin, Applicant provisionally elects, with traverse, specie doxil.

With regard to the election of species from v) modulates subcellular localization of proteosomes, vi) does not alter post-translational processing of an ENaC transcription, vii) modulates transcription of a molecule that regulates ENaC transcription, viii) decreases the level of transcription, ix) modulates transport of molecules to or form the nucleus, x) is an endosomal protease inhibitor, xi) is a cysteine protease inhibitor, xii) is not TPA, or xiii) alters endosomal processing, Applicant provisionally elects, with traverse, specie vii.

With regard to the election of species from xiv) lentiviral, xv) retroviral; xvi) adenoviral, or xvii) adeno-associated viral, Applicant provisionally elects, with traverse, specie adeno-associated viral.

With regard to the election of species from xviii) the selected agent is effective to decrease the level or amount of transcription of one or more subunits of ENaC, xix) the selected agent is effective to decrease the level or amount of transcription of the α, β and γ subunits of ENAC, xx) the selected agent is effective to alter ENaC activity, xxi) the selected agent enhances the efficiency of gene therapy vectors and is effective to decrease the level or amount of transcription of one or more subunits of ENaC and alters the level, amount or activity of a

molecule that alters transcription of one or more ENaC subunit genes, xxii) the selected agent enhances the efficiency of gene therapy and is effective to decrease the level or amount of transcription of one or more subunits of ENaC, xxiii) the selected agent enhances the efficiency of gene therapy vectors and is effective to alter the level, amount or activity of a molecule that alters transcription of one or more ENaC subunit genes, xxiv) the selected proteasome modulating agent is effective to decrease the level or amount of transcription of one or more subunits of ENaC, xxv) the selected proteasome modulating agent is effective to alter the level, amount of activity of a molecule that alters transcription of one or more ENaC subunit genes, xxvi) the selected proteasome modulating agent is effective to decrease the level or amount of transcription of one or more subunits of ENaC and alter the level, amount or activity of a molecule that alters transcription of one or more ENaC subunit genes, xxvii) the selected agent is effective to decrease the level or amount of transcription of the α, β, and γ subunits of ENaC, xxix) the selected agent enhances transduction of viruses which infect mammalian cells and is effective to decrease the level or amount of transcription of one or more subunits of ENaC, xxx) the selected agent enhances transduction of viruses which infect mammalian cells and is effective to alter the level, amount or activity of a molecule that alters transcription of one or more ENaC subunit genes, and xxxi) the selected agent enhances transduction of viruses which infect mammalian cells and is effective to alter the level, amount or activity of a molecule that alters transcription of one or more ENaC subunit genes, Applicant provisionally elects, with traverse, specie xxix.

With regard to the election of species from human cells, canine cells, murine cells, rat cells or rabbit cells, Applicant provisionally elects, with traverse, specie human cells.

Applicant believes claims 1-2, 5-9, 13, 15-23, and 29-32 read on each of the elected species.

Reconsideration and withdrawal of the Restriction Requirement and the election of species, in view of the remarks herein, is respectfully requested.

The Restriction Requirement is traversed on the basis that the inventions are closely related. That is, claims directed to a method to identify one or more agents with dual therapeutic activity in mammalian cells, such as from an agent that inhibits or treats one or more symptoms

of a disease which is associated with aberrant expression or activity of ENaC that also enhances the efficacy of a gene therapy vector or an agent that enhances the efficacy of a gene therapy vector and also alters ENaC expression or activity (claims 1-2, 5-9, 13, 15-23, and 28-32; Group IA) are clearly related to claims directed to methods to identify one or more agents that decrease the level or amount of transcription of one or more subunits of ENaC in mammalian cells (claims 10-32 and 37-84; Group IB).

The Restriction Requirement is also traversed on the basis that Restriction Requirements are optional in all cases. M.P.E.P. § 803. If the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it arguably may include claims to distinct or independent inventions. M.P.E.P. § 803. Moreover, it is submitted that Applicant should not be required to incur the additional costs associated with the filing of multiple divisional applications in order to obtain protection for the claimed subject matter. Due to the relatedness of the subject matter of at least the claims in Group IA and Group IB, the claims in Group IA and Group IB can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner. Evidence that the claims in at least Group IA and Group IB can be efficiently and effectively searched in a single search with no additional burden placed on the Examiner is provided in the Restriction Requirement as those claims are in the same class (class 514) for search purposes.

With regard to the species elections, it is Applicant's position that many of the species elections do not take into consideration the claimed invention, and so are improper. Applicant's Representatives are unclear why such an extensive election of species is needed for a screening method, i.e., a method to identify agents with particular properties.

Moreover, the disclosed species have a disclosed relationship. That is, species i-iv; epoxomicin, doxorubicin, doxil, daunorubicin, idarubicin, epirubicin, aclarubicin, camptothecin, simvastatin, tannic acid and cisplatin; and species v-xiii may be useful as dual therapeutics. With regard to human cells, canine cells, murine cells, rat cells or rabbit cells, the disclosed cells are mammalian cells useful in screening methods. With respect to agents with certain activities (species xviii-xxxi), the agents alter transcriptional activity of ENaC. And with respect to viral vectors, the disclosed vectors are useful to deliver genes to mammalian cells.

Therefore, the Restriction Requirement and species elections are properly traversed, and withdrawal of the Restriction Requirement and election of species is respectfully requested.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6959 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 27th day of March 2007.

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